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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/780,035	GHAYER ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-12 and 14-61* is/are pending in the application.

4a) Of the above claim(s) *39-43 and 47-60* is/are withdrawn from consideration.

5)☒ Claim(s) *37,38* is/are allowed.

6)☒ Claim(s) *5- 12, 14-38, 44-46 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 04/24/2008 has been entered.

Claims 5-12, 16-35 and 61 have been amended.

Claims 5-12 and 14-61 are pending.

Claims 5- 12, 14-38, 44-46 and 61 are under consideration in the instant application.

Claims 39-43, and 47-60 have been withdrawn as being drawn to the non-elected invention.

Claims 1-4 and 13 have been canceled previously.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Office Action will be in response to applicant's amendments/arguments, filed 04/24/2008.

The rejections of record can be found in the previous Office Actions.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

See the previous Office Actions for a more detailed analysis of applicant's arguments.

3. Claims 5- 12, 14-21 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Upon reconsideration of applicant's amended claims, filed 04/28/2008, the previous rejection under 35 USC 112, second paragraph, with respect to the recitation of "IL-18 activity" and "neutralizing antibody" has been withdrawn.

B) Claims 5-12, 14-21 and 24 are indefinite in the recitation of "KG1" because its characteristics are not known. The use of "KG1" as the sole means of identifying the claimed referenced cell line renders the claim indefinite because "KG1" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation to define completely distinct cells.

Amending the claims to include the appropriate ATCC Accession Number would obviate this rejection. See Example 4 on page 36 of the instant specification.

Also, the recitation of "KG1" should be amended to "KG-1" as the proper designation of "KG-1" cell line deposited as ATCC-CCL-246 at the ATCC.

C) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

4. This is a New Grounds of Rejection.

Claims 5-12, 14-21 and 24 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the KG-1 cell line is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell line. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Alternatively, if KG-1 refers to the KG-1 cell line deposited as ATCC CCL-246 at the American Type Culture Collection,
applicant is invited to provide evidence by someone to corroborate the fact that this is so in order to make the record clear in the instant application.

If so, applicant should provide evidence of its public availability without restrictions in order to satisfy the conditions for the deposit of biological materials under 35 USC 112, first paragraph, enablement.

Also, see MPEP 2400.

5. Claims 23-27 and 32-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments, filed 04/28/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant argues the following.

Not in acquiescence of the rejection but in order to expedite allowance of the claims, Applicants have amended the claims to require that any amino acid alterations do not inhibit IL-18 binding. Contrary to the Examiner's contention that the changes in amino acid composition would require undue experimentation to test, Applicants respectfully submit that such experimentation is routine and that Applicants seek appropriate breadth in the claims, for example, so that competitors cannot simply alter an amino acid in order to design around a claim requiring a specific amino acid sequence. Applicants submit that in view of Examiner's concerns regarding the loss of affinity of an antibody due to minor alterations in sequence that claims 25-28 and 32-35 have been amended to require that the "substitution does not inhibit IL-18 binding".

In view of the foregoing amendments and remarks, Applicants respectfully request the removal of the rejection of claims 23-27 and 32-35 under 35 USC § 112, first paragraph.

Again, it is noted that the claims read on "at least one amino acid residue", encompassing multiple amino acid changes and no upper limit to amino acid changes.

Again, the problem here is that the instant specification fails to provide a disclosure of which "at least one amino acid residue" can be substituted or which amino acids are required for the antibody to bind IL-18, but does not inhibit IL-18 binding, broadly encompassed by the claimed invention.

Therefore, there is insufficient direction as to how to make and use the genus of IL-18-specific antibodies, which can have at least amino acid substitution and still bind IL-18, but not inhibit IL-18 binding broadly encompassed by the claimed invention at the time the invention was made and as disclosed in the specification as filed under the written description provision of 35 USC 112, first paragraph.

The following of record is reiterated for applicant's convenience.

It has been well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites.

Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al. (PNAS 79: 1979-1983, 1982). Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function.

Panka et al. (PNAS 85: 3080-3084, 1988) demonstrated that a single amino acid substitution of serine for alanine results in decreased affinity.

In turn, it would have been unpredictable that the anti-CD18 antibodies as defined by the claims which contain "at least one amino acid modification such as a substitution or insertion" of an anti-IL-18 antibody would have the required binding function as well as those "that improve neutralization of IL-18".

The specification does not provide sufficient direction or guidance regarding how to produce anti-CD18 antibodies with any modification, such as any substitution or insertion of any amino acid, as broadly defined by the claims. Undue experimentation would be required to produce the invention commensurate with the scope of the claims from the written disclosure alone.

Without sufficient guidance, it would require undue experimentation of the skilled artisan to make antibodies or antigen-binding fragments thereof which could bind IL-18 and be used in methods of inhibiting IL-18 function that comprised fewer than all six CDRs from a parental antibody that bound IL-18.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Given the recognized unpredictable nature of making antibodies with a desired specificity having any modification, such as any substitution or insertion, from a reference antibody and the lack of sufficient guidance provided in the specification; the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

Applicant's arguments have not been found persuasive.

6. Claims 4-12, 14-24, 44-46 and 61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kucherlapati et al. (US Patent No. 6,075,181, of record) and Dinarello et al. (J. Leukoc. Biol. 1998, 63:658-664. IDS #A4), for the reasons of record set forth in the previous Office Actions.

Applicant's arguments, in conjunction with basic legal principles of obviousness, filed 04/24/2008, have been fully considered, but are not deemed persuasive for reasons or record set forth in the previous Office Actions and reiterated herein, in part, for applicant's convenience.

Applicant argues the following.

Applicants submit that the above-cited references, either singularly or in combination, do not teach, suggest, or motivate one skilled in the art, to make Applicants' human anti-IL-18 antibodies or methods of making the same as recited by the claims as amended.

Dinarello et al. disclose recombinant human IL-18 and identify IL-18 as a potential therapeutic target, and disclose possible "therapeutic options for specific blockade of IL-18", such as neutralizing anti-18 antibodies. Dinarello et al. do not teach, suggest or motivate one skilled in the art to generate fully human antibodies to human IL-18, nor does Dinarello set forth which epitopes such antibodies might be bound to or the dissociation constants and activity of the antibodies generated. In particular, Dinareilo et al. do not teach a human anti-IL-I 8 antibody that dissociates from human IL-18 with a k off rate constant of 0.1slor less, 1 x 102s~or less, 1 x 10-3slor less, 1 x 104s~or less, 1 x 10Ss-lor less, or 1 x 106slor less as determined by surface plasmon resonance, as required by claims 5-10, 16-21,44-46 and 61. Further, Dinareilo et al. do not teach an anti-IL-18 antibody that inhibits human IL-18 activity of IFN-/induction in KG1 cells with an IC50 of 1 x 10-6M or less, 1 x 10-7M or less, 1 x 10SM or less, 1 x 109M or less, 1 x 10l°M or less, or 1 x 10l~M or less, as required by claims 5-10, 16-21, 44-46 and 61. Still further, Dinarello et al. do not teach a human IL-18 antibody that binds an epitope of human IL-18 comprising an amino acid sequence of either SEQ ID NO: 3 or 33 as required by claims 11-12, 14-15, 22-24, and 61.

Kucherlapati et al. disclose a method of generating fully human antibodies to antigens. Kucherlapati et al. do not disclose IL-18 as an antigen. Kucherlapati et al. do not teach, suggest or motivate one skilled in the art to generate fully human antibodies to human IL-18, nor does Kucherlapati set forth which epitopes such antibodies might be bound to or the dissociation constants and activity of the antibodies generated. In particular, Kucherlapati et al. do not teach an anti-IL-18 antibody that dissociates from human IL-18 with a koff rate constant of 0.1slor less, 1 x 10-2slor less, 1 x 103sqor less, 1 x 10-4s-lor less, 1 x 10 5s-l or less, or 1 x 106slor less as determined by surface plasmon resonance, as required by claims 5-10, 16-21, 44-46 and 61. Further, Kucherlapati et al. do not teach an anti-IL-18 antibody that inhibits human IL-18 activity of IFN-), induction in KG1 cells with an IC50 of 1 x 10-6M or less, 1 x 107M or less, 1 x 10 8M or less, 1 x 10-9M or less, 1 x 10-1°M or less, or 1 x 10-11M or less, as required by claims 5-10, 16-21, 44-46 and 61. Still further, Kucherlapati et al. do not teach a human IL- 18 antibody that binds an epitope of human IL-18 comprising an amino acid sequence of either SEQ ID NO: 3 or 33 as required by claims 11-12, 14-15, 22-24, and 61.

The Examiner asserts that one of ordinary skill in the art would have been reasonably expected to combine the teaching of Dinarello et al. with those of Kucherlapati et al. to produce Applicants' antibodies. Even though neither reference teaches explicitly a human monoclonal antibody to human IL\-l8, the Examiner asserts that it would be "instantly obvious" to one of ordinary skill in the art to combine, the teaching of Dinarello et al. and Kucherlapati to arrive at Applicants' invention. However, without Applicants' disclosure, it is not obvious to one skilled in the art to make a leap from various therapeutic options as a clinical strategy to block IL-18 to one specific cure, namely a fully human anti-IL-18 antibody as described in the claims as amended with certain affinity and which binds to a particular epitope of IL-I 8.

The mere "[r]ecognition of the problem ... does not render obvious the eventual solution. Recognition of a need does not render obvious the achievement that meets that need. There is an important distinction between the general motivation to cure an uncured disease (for example, the disease of multiple forms of heart irregularity), and the motivation to create a particular cure." Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc. 381 F.3d 1371,1377 (2004). Like Cardiac Pacemakers, the Dinerello et al disclosure of IL-18 as a potential target in inflammatory disease, at best, serves as recognition of a problem (i.e., IL-18 mediated disease), with no motivation to seek out, to investigate, or to explore the potential use of a fully human antibody to human IL-18 that has Applicants claimed characteristics as a solution. Kucherlapati et al. do not provide any motivation to create a particular cure or suggest IL-18 as an antigen (much less human IL-18). None of the cited art, singularly or in combination, provides any teaching, suggestion or motivation to arrive at Applicants' invention of a specific cure, a human anti-IL-18 antibody to human IL-18 as presently claimed.

In conclusion, Applicants assert that the Examiner fails to provide the requisite "clear and particular showing" of any suggestion or motivation to combine the cited references. The combination of the cited art is made by the Examiner, upon guidance, direction, and motivation to do so, by Applicants' present invention. Such hindsight reconstruction is impermissible as a basis for rejection under 35 USC §103. (see MPEP § 2142). Because the cited art fails to satisfy the criteria necessary to establish or to sustain rejection of claims 5-12, 14-24, 44-46 and 61 as

obvious under 35 USC §103(a). In view of the foregoing remarks, Applicants respectfully request withdrawal of the rejection of claims 5-12, 14-24, 44-46 and 61 under 35 USC § 103(a).

Applicant's arguments and the examiner's rebuttal are essentially the same of record. See the previous Office Actions for a more detailed analysis of applicant's arguments.

Again, applicant's arguments have not been found persuasive for the following reasons.

Again, in response to applicant's continual argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case as noted previously, the teaching, suggestion, or motivation to make the claimed antibody can be readily found in the cited references as Dinarello teaches availability of human IL-18, the involvement of IL-18 in clinical pathology as that antibodies to IL-18 can inhibit the in vivo production of other pro-inflammatory cytokines, and that neutralizing anti-IL-l8 antibodies are a therapeutic option for specific blockade of IL-18.

Additionally as noted previously, Kucherlapati teaches a method of producing fully human monoclonal antibodies to any protein of interest, but especially cytokines, and advantages of such antibodies in avoiding the undesired immune responses elicited by administering non-human antibodies to humans. Therefore, it is instantly obvious to a person having ordinary skill in the art to combine the teachings of the cited references and to make the human anti-IL-18 antibodies as claimed for the purpose of disease treatment using the method taught by Kucherlapati.

Again, in contrast to applicant's continued arguments that without applicants disclosure, it is not obvious to make a leap from various therapeutic options as clinical strategy to block IL-18 to one specific cure, namely a human anti-IL-18 antibody, or to combine the teachings of the two references to arrive at applicants invention;

this argument has not been found persuasive because none of the teachings, from which the instant rejection relies upon, is from applicants disclosure, instead they are all from the cited prior art references.

Again, applicant has argued in conjunction with Cardiac Pacemakers Inc. v. St. Jude Medical, Inc. 381 F.3d 1371, 1377 (2004), that recognition of a need does not render obvious the achievement that meets that need, and there is an important distinction between the general motivation to cure an uncured disease and the motivation to create a particular cure, that none of the cited art singularly or in combination, provides any teaching, suggestion, or motivation to arrive at applicants invention, and that a disclosure of a method to generate human monoclonal antibodies, combined with a reference disclosing neutralizing anti-IL-18 antibodies is not a clear and particular teaching, suggestion, or motivation to make the fully human anti-IL-18 antibody of the present invention.

Again, this argument has not been persuasive for the following reasons. First, if either reference had explicitly taught the antibody as claimed, the present invention would have been rejected under 35 U.S.C. 102.

Further, besides the reasons addressed above, the cited case law does not apply in the instant situation because in addition to the teachings of neutralizing anti-IL-18 antibodies, more importantly, Dinarello clearly teaches (1) the pathological role of IL-18 in disease development as that IL-18 is evolving as a major as a pro-inflammatory cytokine with implications for a role in inflammatory and infectious diseases, and it may also be a player in autoimmune diseases (page 658, the right column), and anti-IL-18 antibodies suitable for treating human diseases, and (2) neutralizing anti-IL-l8 antibodies are a therapeutic option for specific blockade of IL-18. Furthermore, though Dinarello does not teach a human anti-IL-18 antibody or a method of making such, Kucherlapati teaches a method of producing fully human monoclonal antibodies to any protein of interest, but especially cytokines, and advantages of such antibodies.

Again, in contrast to applicant's assertions, the combined teachings provide strong teaching, suggestion, or motivation to arrive at applicant's invention.

Again, applicant has argued that the combination of the cited art is made by the examiner, upon guidance, direction, and motivation to do so, by applicant's present invention, and that this is hindsight reconstruction and is impermissible as a basis for 103 rejection.

Again, this argument has not been found persuasive for the reasons addressed above. In addition, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Also, the arguments of counsel cannot take the place of objective evidence in the record. In re Schulze, 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01(c).

One cannot show nonobviousness by attacking references individually where the rejections art based on combinations of references. In re Keller , 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc. , 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).
See MPEP 2145.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdiqital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to provide inhibitory anti-IL-18 antibodies for diagnostic and therapeutic utilities in humans,
incorporating the claimed functional and structural characteristics such as human antibodies with certain dissociation constants and epitopic specificities were implicit as well as routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such inhibitory anti-IL-18 antibodies for human therapeutic / diagnostic utilities

Applicant's arguments have not been found persuasive.

7. Claims 37 and 38 are allowable.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

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